



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,998	12/18/2006	Charles Sfeir	250030	7502
23460 7590 09/15/2008 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731				
EXAMINER SAIDHA, TEKCHAND				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
09/15/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,998

Applicant(s)

SFEIR ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) 1-84 and 87-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

1. Claim 1-98 are present in this application.

2. ***Election***

Applicant's election of Group VII (claims 85-86, SEQ ID NO: 1 & 2) is acknowledged.

3. Applicants note that claims 83-84 and 90-98 are deemed to link Group VII and VIII (Office Action, page 5). Applicants understand that these linking claims will be examined and that, upon allowance, the claims of Group VIII will also be examined. Applicants further note that the Office Action relates the claims of Groups VII and Groups I, III, and V and relates the claims of Group VIII with Groups II, IV, and VI as product and process of use (Office Action, pages 8-9). Applicants understand that, upon allowance of the claims of Group VII that the claims of Groups I, III, and V will be considered for rejoinder and that upon allowance of the claims of Group VIII, the claims of Groups II, IV, and VI will be considered for rejoinder.

In response to the restriction requirement stated in the Office Action at page 10, between SEQ ID Nos. 1 and 2 and between SEQ ID Nos. 3 and 4, applicants elected SEQ ID NOs: 1 and 3, with traverse. The traversal is that the species SEQ ID NOs: 1 and 2 and SEQ ID NOs: 3 and 4 are sufficiently few in number such that a search and examination of the sequences will not impose an undue burden. This is analogous to a situation involving a Markush claim with few species (See MPEP 803.02). Moreover, claim 83, which is stated by the Office to be generic and a linking claim, must be examined throughout its full scope, and restriction within the claim is improper.

In response, the linking claims will be considered upon allowance of the elected claims, provided they meet all the requirements for patentability. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented

prior to final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

Regarding Applicants traversal that the species SEQ ID Nos: 1 and 2 and SEQ ID Nos: 3 and 4 are sufficiently few in number such that a search and examination of the sequences will not impose an undue burden, Is considered but not found to be persuasive because SEQ ID NO: 3 and SEQ ID NO: 4 (nucleotides sequences) are not only distinct from SEQ ID Nos: 1 & 2 (amino acid sequences) but would involve a serious burden of search on the Examiner - by way of searching for additional commercial and US patent sequence data bases apart from Non-Patent literature (NPL) searches. Further, the species election of BMP is not relevant to the elected claims.

4. Elected Claims 85-86 with respect to SEQ ID NO: 1 & 2 are under consideration in this Office Action.

Claims withdrawn:

Claims 1-84 & 87-98 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. ***Continuation of prior application***

When a non-provisional application claims the benefit under 35 USC 120 of a prior application, which in turn claims the benefit of a provisional application, the first sentence of the specification should read, e.g., "This application is a continuation of U.S. Application No. 08/-----, filed -----, now abandoned, which claims the benefit of U.S. Provisional Application No. 60/-----, filed -----." Also, the present status of all parent applications should be included.

6. ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e), filed 8 August 2003, is acknowledged.

7. ***Drawings***

The informal drawings (Figures 22 and 23 only) are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) is required in reply to this Office action. The replacement sheet(s) should

be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

8. ***Sequence Rules***

The instant specification on page 31, Table 1, present primer sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of four or more residues or 10 or more nucleotides must be identified by a SEQ ID NO. The amino acid sequences disclosed in Table 1 must be identified by appropriate SEQ ID Nos. In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NO.; and where required provide a new version of the sequence listing and disk.

Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. j 1.821(e) or 1.821(9) or 1.821(g) or 1 .825(d), as well as an amendment directing its entry into the specification.

9. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

10. Claim Rejections - 35 USC § 112 (second paragraph)

Claims 1-2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'a fragment thereof' or a derivative of either of forgoing'. The claim is unclear about the claim language encompassing either of forgoing'. The specification fails to provide a yardstick of the fragment size or the way the sequence derivatives is prepared and the specification provide a definition. Thus the meets and bounds of the claims are unclear.

Claim 2 is included in the rejection for failing to correct the defect present in the base claim(s).

11. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 85 is rejected under 35 U.S.C. 102(e) as being anticipated by Kong et al. [USP 7,396,644]. Kong et al. teach a human dentin sialophosphoprotein or DSPP sequence of SEQ ID NO: 2, which is 68.2% identical to the instantly claimed SEQ ID NO: 1 fragment or derivative; and 74.5% identical to instantly claimed SEQ ID NO: 2. [See the enclosed sequence search alignments]. The reference anticipates claim 85 only.

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached between 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tekchand Saidha/
Primary Examiner, Art Unit 1652
Recombinant Enzymes, 02A65 Remsen Bld.
400 Dulany Street, Alexandria, VA 22314
Telephone: (571) 272-0940
September 11, 2008